REMARKS

This Amendment is responsive to the Final Office Action dated April 16, 2008.

Applicant has amended dependent claim 34 to correct a minor typographic error resulting from the previous Amendment submitted by Applicant on December 10, 2007. Applicant's amendment to claim 34 does not present any new issues that would require additional consideration or searching by the Examiner. Therefore, Applicant respectfully requests entry of this Amendment.

Upon entry of the Amendment, claims 1-9, 11-31, and 33-36 would remain pending.

Withdrawal of Finality of the Office Action

Applicant requests withdrawal of the finality of the Office Action. The Final Office Action did not address all pending claims in the Application. For example, the Final Office Action did not address claim 33. Neither the Final Office Action nor the Office Action Summary accompanying to the Final Office Action referred to the claim 33 or indicated that claim 33 was pending. However, claim 33 was presented in the Application as originally filed, and neither the Applicant nor Examiner has cancelled or withdrawn claim 33 prior to the Final Office Action. Applicant respectfully requests that the Examiner address claim 33.

As another example, the Final Office Action did not address pending claim 36, which Applicant added to the Application in the previous Amendment filed December 10, 2007. Although the Office Action Summary accompanying the Final Office Action indicated that claim 36 was pending and was rejected, the Final Office Action did not address claim 36 or its disposition as either allowed or rejected.

For at least these reasons, Applicant respectfully requests withdrawal of the finality of the Office Action and issuance of a new Office Action that addresses claims 33 and 36.

Allowable Subject Matter

In the Final Office Action, the Examiner objected to claims 19-26 as being dependent upon a rejected base claim, but indicated that such claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Office Action Summary indicated that claims 19-26 were rejected, contrary to the indication of allowable subject matter in the body of the Final Office Action. It appears that the Examiner may have intended to object to claims 19-26 but inadvertently indicated that the respective claims were rejected in the Office Action Summary. Applicant assumes that claims 19-26 were not rejected in the Final Office Action, but would appreciate clarification of this point.

Claim Rejection Under 35 U.S.C. § 112

In the Final Office Action, the Examiner rejected claim 34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As a basis for the rejection, the Office Action indicated that claim 34 was dependent on a non-existent claim (claim 32).

In this Amendment, Applicant has amended claim 34 to properly depend from claim 29. Applicant submits that claim 34, as amended, meets the requirements of 35 U.S.C. 112, second paragraph. Therefore, withdrawal of the rejection is respectfully requested.

Claim Rejection Under 35 U.S.C. § 102

In the Final Office Action, the Examiner rejected claims 1-5, 7-9, 27-29, 31, and 35 under 35 U.S.C. 102(e) as being anticipated by Bourgeois (US 6,216,039).

Applicant respectfully traverses the rejection. Bourgeois fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(e), and provides no teaching that would have suggested an apparent reason to include such features.

Independent claim 1 recites a system for gastric stimulation of a patient comprising sensing electrodes for sensing intrinsic gastric activity from a stomach wall of a patient, an implantable gastric stimulator coupled to the sensing electrodes, and stimulation electrodes for conveying the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient. Per claim 1, the implantable gastric stimulator receives the sensed intrinsic gastric activity and performs an analysis of the sensed intrinsic gastric activity to classify the activity as normal or abnormal, and determines whether to create an electrical stimulation based at least in part upon the classification of the sensed intrinsic gastric activity as normal or abnormal. The

electrical stimulation is configured for disrupting the normal gastric activity of the stomach, as recited in claim 1.

The Final Office Action, with regard to claims 1, 27, 29, 34 and 35, stated that:

> Bourgeois discloses a system for gastric stimulation that utilizes a plurality of sensing electrodes (5) and a plurality of stimulating electrodes (4) placed in the stomach for sensing intrinsic activity (e.g. Fig. 1). Bourgeois further discloses that it classifies the intrinsic activity as normal or abnormal and then stimulates the stomach with different stimulation parameters based on the classification (e.g. Fig. 7, see steps 7-8 and 7-14 which determine if normal waves are occurring and if so provides stimulation therapy at step 7-9).

On this basis, the Final Office Action concluded that Bourgeois anticipates claims 1, 27, 29, 34, and 35. Applicant respectfully disagrees.

In general, Bourgeois describes an apparatus and method for diagnosing and treating irregular gastric rhythms such as bradygastria and tachygastria.[1] As described by Bourgeois, the apparatus includes, *inter alia*, a sensor to sense slow waves and determines whether the slow waves are occurring in an irregular or unstable manner.[2] The apparatus further permits the sensed slow waves to be diagnosed as being part of a bradygastria or a tachygastria and, in response, provides appropriate electrical stimulation delivered to the stomach of a patient.[3]

For example, Figure 7 of Bourgeois, cited by the Examiner in the Final Office Action, generally illustrates steps used by such an apparatus to normalize irregular slow waves by sensing slow waves, determining whether the slow waves are outside of a normal slow wave band, and delivering electrical stimulation to normalize the slow waves when they are outside of the normal band.[4] Initially, the rate of sensed slow waves is determined and compared to a range of values that are defined based on a normal slow wave rate (7-2).[5, 6]

In the example shown in FIG. 7 of Bourgeois for treating the stomach, the range of 2.7 to 3.3 beats per minute (bpm) is defined as the normal slow wave rate.[7] If the sensed slow wave rate is outside of the normal range, then steps are taken to characterize the nature of the sensed

---

[1] Bourgeois, Abstract.
[2] *Id.*
[3] *Id.*
[4] *Id.* at Column 8, line 60 to Column 9, line 67; FIG. 7.
[5] *Id.* at col. 9, lines 1-11.
[6] Applicant notes that Y/N indicators out of decision block 7-2 FIG. 7 appear to be incorrectly labeled and should instead be switched with one another based on the description of FIG. 7 in Bourgeois starting at line 1 of column 7.
[7] *Id.* at col. 9, lines 3-7.

irregular slow waves, and deliver appropriate electrical stimulation to normalize the slow wave rate based on the characterization.

If the sensed slow wave is normal, however, the Bourgeois device continues to monitor the slow-wave (7-2) until the slow wave rate is outside the normal range. In this case, the process proceeds to block 7-3. Applicant notes that the "Y" and "N" associated with block 7-2 appear to be reversed, as the text of the Bourgeois patent refers to proceeding to block 7-3 when the answer to the query in block 7-2 is "yes."

As further described by Bourgeois, if the slow rate is determined to be below 2.5 bpm for a specified amount of time, electrical stimulation is delivered that is configured to increase the slow wave rate.[8] Conversely, if the slow wave rate is higher than the normal rate for a specified amount of time, electrical stimulation is delivered that is configured to decrease the slow wave rate.[9]

In each case, however, the electrical stimulation (represented by blocks 7-7 and 7-13, respectively) is configured to return the slow wave to a normal rate i.e., to normalize the slow wave rate, when the slow wave rate is determined to be irregular, rather than conveying electrical stimulation for disrupting normal gastric activity of the stomach, as required by independent claim 1.

As further indicated by FIG. 7, the delivery of electrical stimulation is repeated until the sensed slow wave rate returns to a desirable value. Blocks 7-8, 7-14, and 7-9 illustrate that stimulation therapy labeled as "normal stimulation therapy" is provided only when the slow wave rate returns to a desirable value. The Examiner characterized this portion of FIG. 7 as determining if normal waves are occurring and, if so, providing stimulation therapy. However, the "normal stimulation therapy" provided in block 7-9 is not for disrupting normal gastric activity of the stomach, as recited in claim 1. On the contrary, the "normal stimulation therapy" appears to be configured to maintain the slow wave frequency at a normal rate.

Bourgeois describes examples of "normal stimulation therapy" as providing electrical stimulation only upon the absence of intrinsic slow wave as detected by the device, or providing electrical stimulation when a demand for such stimulation is sensed by the device.[10] Notably,

---

[8] *See e.g.*, blocks 7-4 to 7-8 of FIG. 7.
[9] *See e.g.*, blocks 7-10 to 7-14 of FIG. 7.
[10] *Id.* at col. 9, lines 61-67.

Bourgeois fails to teach or disclose that "normal stimulation therapy" includes electrical stimulation to disrupt normal gastric activity of the stomach, as set forth in Applicant's claims. Indeed, this would seem to be at odds with the objectives of restoring and maintaining a normal slow wave in the cases of bradygastria and tachygastria.

Consequently, in contrast to the features recited by claim 1, Bourgeois fails to teach or disclose stimulation electrodes for conveying the electrical stimulation from an implantable gastric stimulator to the stomach wall of the patient, wherein the electrical stimulation is for disrupting normal gastric activity of the stomach. To the contrary, Bourgeois appears to describe delivery of electrical stimulation when irregular gastric rhythms, such as slow waves at an abnormal rate, are sensed. As previously explained, the apparatus of Bourgeois delivers electrical stimulation that is configured to normalize the slow wave rate, and then provides stimulation designed to maintain the slow waves at a normal rate after the irregular slow waves have been returned to a normal rate.

Bourgeois provides no teaching that would have suggested any apparent reason for modification to incorporate the features recited by claim 1. As outlined above, Bourgeois generally describes the use of electrical stimulation to return irregular gastric rhythms to normal rates. Accordingly, conveying electrical stimulation to the stomach to disrupt normal gastric activity, as recited by claim 1, would seem to be directly contrary to the teachings of Bourgeois. Instead, it would appear that Bourgeois would suggest maintaining sensed gastric activity that is normal at a normal level instead of conveying electrical stimulation for disrupting normal gastric activity.

Applicant respectfully notes that the Examiner's characterization of Bourgeois did not address all the requirements of claim 1. For example, the Examiner stated that "Bourgeois discloses that it classifies the intrinsic activity as normal or abnormal and then stimulates the stomach with different stimulation parameters based on the classification (e.g. Fig. 7, see steps 7-8 and 7-14 which determine if normal waves are occurring and if so provides stimulation therapy at step 7-9)." However, Applicant points out that even if Bourgeois did disclose subject matter consistent with this characterization, Bourgeois still would not teach all features of claim 1. Most notably, the characterization does not address the feature of electrical stimulation for disrupting normal gastric activity of the stomach.

For at least these reasons, Bourgeois fails to teach or disclose each and every limitation set forth in independent claim 1. Applicant respectfully requests withdrawal of the rejection.

Claim 29, claim 29 recites a method for gastric stimulation of a patient comprising sensing intrinsic gastric activity on the stomach wall of a patient, classifying the sensed intrinsic electrical gastric activity as normal or abnormal; determining when to apply electrical stimulation to the stomach wall of the patient based upon the classification of the sensed intrinsic gastric activity as normal or abnormal, forming an electrical signal in response to the determining when the sensed intrinsic gastric activity is classified as normal; and disrupting normal gastric activity of the stomach with the electrical signal.

The Examiner used the same basis to reject claim 29 as used to reject claim 1. In general, the deficiencies of Bourgeois identified with respect to claim 1 also apply to independent claim 29. For example, claim 29 requires disrupting normal gastric activity of the stomach with an electrical signal. Claim 29 explicitly states that the electrical signal is formed in response to the determining when the sensed intrinsic gastric activity is classified as normal. However, as previously explained, Bourgeois fails to disclose or suggest disrupting normal gastric activity of the stomach with an electrical signal, much less an electrical signal that is formed in response to the determining when the sensed intrinsic gastric activity is classified as normal.

Independent claim 35 recites a system comprising sensing electrodes for sensing intrinsic electrical gastric activity from a stomach wall of a patient, an implantable gastric stimulator coupled to the sensing electrodes, wherein the implantable gastric stimulator receives the sensed intrinsic electrical gastric activity and classifies the activity as normal or abnormal, and wherein the stimulator creates electrical stimulation when the sensed intrinsic electrical gastric activity is classified as normal, and stimulation electrodes for conveying the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient. Per claim 35, the electrical stimulation is configured to disrupt normal gastric activity of the stomach.

The Examiner used the same basis to reject claim 35 as used to reject claims 1 and 29. In general, at least some of the deficiencies of Bourgeois identified with respect to claims 1 and 29 also apply to independent claim 29. Bourgeois fails to disclose or suggest, for example, an electrical stimulation configured to disrupt normal gastric activity of the stomach, much less that

the implantable gastric stimulator creates the electrical stimulation when the sensed intrinsic electrical gastric activity is classified as normal.

With respect to dependent claims 2-5, 7-9, 27-29, and 31, these dependent claims are all either directly or indirectly dependent on independent claim 1 or claim 29. As such, the dependent claims include the limitations of their respective independent claim. For the reasons previously stated, Bourgeois does not teach or disclose all features of independent claims 1 and 29, therefore, does not teach or disclose all features of claims 2-5, 7-9, 27-29, and 31.

For at least these reasons, Bourgeois fails to disclose each and every limitation set forth in claims 1-5, 7-9, 27-29, 31, and 35. Accordingly, the final Office Action did not establish a prima facie case for anticipation of Applicant's claims 1-5, 7-9, 27-29, 31, and 35 under 35 U.S.C. 102(b). Applicant respectfully requests withdrawal of this rejection.

Claim Rejection Under 35 U.S.C. § 103

In the Final Office Action, the Examiner rejected claims 6, 11-18 and 30 under 35 U.S.C. 103(a) as being unpatentable over Bourgeois as applied to claims 1 and 7 above, and further in view of Gordon (US 6,895,278). Applicant respectfully traverses the rejection.

The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested an apparent reason to arrive at the claimed invention.

Dependent claims 6, 11–18 and 30 are all either directly or indirectly dependent on independent claim 1 or claim 29. As such, the dependent claims include the limitations of their respective independent claim. For the reasons previously stated, Bourgeois does not teach or disclose all features of independent claims 1 and 29 and, therefore, does not teach or disclose all features of claims 6, 11–18 and 30. Furthermore, these identified deficiencies are not overcome by the teachings of Gordon.

In addition, Gordon fails to teach or disclose the feature of the stimulator temporarily reverting to a power conserve condition in the absence of a programmable threshold of normal activity, as required by claim 11. While Gordon describe using a programmable calendar 48 in FIG. 3 to provide increased stimulation at certain hours of the day, and decreased stimulation at other hours of the day, the specific times of providing decreased stimulation appear to be

preprogrammed times based on when gastric activity is estimated to be less than other times of the day.[11] On the contrary, claim 11 requires that the stimulator revert to a power conservation condition in the absence of a programmable threshold of normal activity, rather than preprogrammed time periods as described by Gordon.

For this additional reason, Bourgeois and Gordon, viewed in combination or individually, fail to teach or disclose the requirements of dependent claim 11, and dependent claims 12-18, which are all either directly or indirectly dependent on claim 11.

Furthermore, Gordon fails to teach or disclose maintaining a history of predecessor electrical events, as required by claim 30. While Gordon describes a device including a memory provided to store data,[12] Gordon makes no mention of maintaining a history of predecessor events, much less predecessor electrical events.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 6, 11–18 and 30 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

Claims 33 and 36

As previously noted, the Office Action failed to address claims 33 and 36 in the Final Office Action. Specifically, claims 33 and 36 are not listed in the Final Office Action under any of the rejections or the objections.

The Office Action Summary indicated that claim 36 was rejected in the Final Office Action. However, the Office Action did not mention claim 36, or identify a basis for rejecting claim 36 in the Final Office Action.

None of references cited in the Final Office Action, either alone or in combination, disclose or suggest the features of independent claim 36. In particular, the cited references fail to suggest a method comprising sensing intrinsic electrical gastric activity from a stomach wall of a patient; classifying the intrinsic electrical gastric activity as normal or abnormal, applying electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as normal, wherein the electrical stimulation is configured to disrupt normal gastric activity of the

[11] *See* Gordon, column 10, line 44 to column 11, line 41.
[12] Gordon, column 5, lines 1-3.

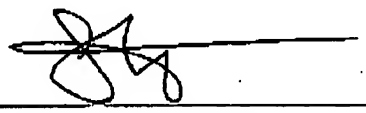
stomach, and withholding application of electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as abnormal, as recited by independent claim 36.

Applicant respectfully requests that the Examiner clarify the disposition of claims 33 and 36 and provide a full examination of the claims on the merits.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 6-16-08

By: 

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.286.8342
Facsimile: 651.735.1102

Name: Steven J. Shumaker
Reg. No.: 36,275